

REMARKS/ARGUMENTS

Claims 1-2 and 5-20 are pending in the application. Claims 3-4 are canceled. The Applicants have amended claims 1, 5, 7-8, 10, 12 and 13. No new matter is added by the amendments. Support for the claims as amended is found in the specification as filed. Reconsideration and allowance of all pending claims are respectfully requested.

In the Office Action on page 2, paragraph 2 claims 1-20 stand rejected under USC §112, second paragraph. By the foregoing amendments substituting the term "DHA" with docosahexaenoic acid, the Applicants submit that the rejection is overcome. Applicants request the rejection be withdrawn.

In the Office Action on page 3, paragraph 4, claims 1-4, 9 and 15 stand rejected under 35 USC §102 as being anticipated by WO 99/53777 ("777" or "the '777 reference"). Based on the foregoing amendment this rejection is overcome. Claim 1 as amended recites a pharmaceutical or dietary composition consisting of (a) one or more vitamins, (b) one or more minerals selected from the group consisting of Iron, Zinc and Magnesium, (c) one or more trace elements selected from the group consisting of Chromium, Copper, Iodine, Molybdenum and Selenium, (d) docosahexaenoic acid (DHA), and (e) a pharmaceutically or dietetically suitable carrier. Claim 1 as amended does not contemplate calcium as a possible ingredient. In the present application the problem was recognized that the pharmaceutical or dietary compositions of the prior art for pregnant women are not widely accepted by pregnant women, because tablets containing these pharmaceutical or dietary compositions of the prior are rather voluminous and therefore hard to swallow. This problem has been solved by the claimed compositions of the present application. It has been found that the ingredient calcium in combination with the high amount of vitamins is responsible for the comparably voluminous dosage forms which are - in particular for pregnant women suffering from morning sickness - hard to swallow (see present application on page 2, lines 24-26 and on page 3, lines 8-10 and 17-27 and on page 4, lines 14 and 15). Compositions without calcium - like the compositions of amended claim 1 (and claim 10 discussed further hereinbelow) and the claims dependent thereon, are less voluminous, are easier to swallow and are therefore better accepted by pregnant women.

Conversely, the '777 reference discloses a composition for pregnant and lactating women comprising **calcium**, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (see page 2, last paragraph of '777). In all Examples 1 to 4 of '777 calcium is present in significant amounts. The '777 reference stresses the importance of calcium as a required component of the invention, to fulfill a need of pregnant and lactating women who otherwise may not be able to obtain the required amount of calcium from their diet (see pages 1-2 of '777). Thus, amended claim 1 is novel over the '777 reference. Claims 3-4 are canceled. Claims 2, 9 and 15 all depend from claim 1 and recite additional features, therefore these claims are also novel over the '777 reference. Applicants request this rejection be withdrawn.

In the Office Action on page 3, paragraph 6, claims 5 to 8 stand rejected under 35 USC §103 as obvious over the '777 reference. Applicants traverse this rejection. Claims 5 to 8 depend from amended claim 1, recited above, and recite additional features. The shortcomings of the '777 reference discussed above make clear that the '777 reference teaches away from the presently claimed composition for pregnant and lactating women which does not include calcium. One skilled in the art reading the '777 reference would be led to include calcium in a composition for pregnant and lactating women, rather than specifically exclude it, as in the presently claimed invention. As such, claims 5-8 of the subject application are not obvious over the '777 reference, and applicants request this rejection be withdrawn.

In the Office Action on page 4, paragraph 8, claims 5-8, 10-13 and 16-20 stand rejected under 35 USC §103 as obvious over the '777 reference in view of Uiterwaal et al. (US 4710387)("Uiterwaal et al."). Applicants traverse based on the foregoing amendments and arguments. Claims 5-8 depend from claim 1 and have been discussed above. Claim 10 as amended recites a pharmaceutical or dietary composition consisting of (a) a multi-vitamin mixture consisting of β -carotene, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D₃, Vitamin E, Folic Acid, Biotin and Niacinamide; (b) a mineral mixture consisting of Iron, Zinc and Magnesium; (c) a mixture of trace elements consisting of Chromium, Copper, Iodine, Molybdenum and Selenium; (d)

docosahexaenoic acid; and (e) a pharmaceutically or dietetically suitable carrier. Claim 10 as amended, and claims 11-13 and 16-20 which are dependent thereon, do not include calcium in the claimed composition.

The shortcomings of the '777 reference are discussed hereinabove and are incorporated by reference. A skilled artisan viewing the '777 reference would not be motivated to look to Uiterwaal et al. to solve the shortcomings of the '777 reference, since the '777 reference teaches away from the presently claimed invention. Neither the '777 reference nor Uiterwaal et al. teach or suggest that the presence of calcium in the composition influences the volume or acceptance of the dosage form. Moreover, the combination of the '777 reference and Uiterwaal et al. does not result in the presently claimed invention. Uiterwaal et al. concerns a nutritional supplement preparation for pregnant and breast-feeding women comprising proteins, fat, carbohydrates, minerals such as calcium, phosphorus, magnesium, iodine and trace elements such as zinc, iron, copper and vitamins (see claim 9 of Uiterwaal et al.). All of the examples of Uiterwaal et al. (see examples 1-3) contain significant amounts of calcium (see examples 1 and 2: 17.90 kg Ca-caseinate and 3.35 kg di-Ca-phosphate-2-hydrate; example 3: 860 mg calcium, and see page 1, column 2, lines 15-24 "600-1000 mg calcium"). As such, Uiterwaal et al. cannot cure the shortcomings of the '777 reference. The combination of the cited references results in a composition that must contain calcium. All of the rejected claims exclude calcium from the claimed composition. Accordingly, the rejection of claims 5-8, 10-13 and 16-20 is overcome by the foregoing amendments. Applicants request this rejection be withdrawn.

In the Office Action on page 5, paragraph 9 claim 14 stands rejected under 35 USC §103 as obvious over the '777 reference in view of Drug Development and Industrial Pharmacy 12 (8&9) 1133-1144 (1986) by Jimerson ("Jimerson"). Jimerson teaches merely a soft gelatin capsule as a dosage form. Neither the '777 reference nor Jimerson teach or suggest the invention of claim 10, from which claim 14 depends. Accordingly, the rejection of claim 14 is overcome by the foregoing amendments. Applicants request this rejection be withdrawn.

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In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

Respectfully submitted,

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